STENT WITH ENHANCED CROSSABILITY

FIELD OF THE INVENTION

The present invention generally relates to implantable intraluminal medical devices, particularly stents. The present invention relates to an implantable intraluminal device which is useful for repairing or serving as a conduit for vessels narrowed or occluded by disease or for use in other body passageways requiring reinforcement or the like. More specifically, the present invention discloses an alignment of a flexible connector within a stent which decreases the likelihood of the stent's catching on a non-smooth surface.

BACKGROUND OF THE INVENTION

As background to a discussion of stents, one notes that in the 1970s, the technique of percutaneous transluminal coronary angioplasty (PTCA) was developed for the treatment of atherosclerosis. Atherosclerosis is the build-up of fatty deposits or plaque on the inner walls of a patient's arteries; these lesions decrease the effective size of the artery lumen and limit blood flow through the artery, prospectively causing a myocardial infarction or heart attack if the lesions occur in coronary arteries that supply oxygenated blood to the heart muscles. In the angioplasty procedure, a guide wire is inserted into the femoral artery and is passed through the aorta into the diseased coronary artery. A catheter having a balloon attached to its distal end is advanced along the guide wire to a point where the sclerotic lesions limit blood flow through the coronary artery. The balloon is then inflated, compressing the lesions radially outward against the wall of the artery and

substantially increasing the size of its internal lumen, to improve blood circulation through the artery.

Presently, it is the case that stents are increasingly being used in place of or in addition to PTCA for treatment of atherosclerosis, with the intent of minimizing the need to repeatedly open an atherosclerotic artery. Although a number of different designs for stents have been published, stents are generally configured as elongate cylindrical structures that are provided in a first state and can assume a second, different state, with the second state having a substantially greater diameter than the first state. A stent is implanted in a patient using an appropriate delivery system for the type of stent being implaced within the patient's arterial system. There are two basic types of stents--those that are expanded radially outward due to the force from an inflated angioplasty type balloon, such as the Bx Velocity® and Palmaz-Schatz® stents, made by Cordis Corporation, and those that are self expanding, such as the SMART® stent, made by Cordis Corporation.

Generally, stents, grafts, and graft stents are implantable medical devices (sometimes termed implantable tubular prostheses) which are placed within blood vessels and other body passageways to treat disease conditions such as stenoses, occlusions, and aneurysms. That is, a stent is used as a tubular structure left inside the lumen of a duct to relieve an obstruction. Commonly, stents are inserted into the lumen in a non-expanded form and are then expanded autonomously (or with the aid of a second device in situ. A typical method of expansion occurs through the use of a catheter mounted angioplasty balloon which is inflated within the stenosed vessel or body passageway in order to shear and disrupt the

obstructions a associated with the wall components of the vessel and to obtain an enlarged lumen. Transluminal implantation of such devices requires that they be introduced to the site collapsed about or within an introduction device and released to self expand or are expanded by other mechanisms to an expanded tubular state providing a lumen of approximately the same size as the patent vessel or duct lumen.

In the absence of a stent, restenosis may occur as a result of elastic recoil of the stenotic lesion. A number of stent designs have been reported. Such stents include those with rigid ends (8 mm) and a flexible median part of 7-21 mm. This device is formed of multiple parts and is not continuously flexible along the longitudinal axis. Other stent designs with rigid segments and flexible segments have also been described.

Other stents are described as longitudinally flexible but consist of a plurality of cylindrical elements connected by flexible members. These designs have at least one disadvantage if, for example, protruding edges occur when the stent is flexed around a curve, raising the possibility of inadvertent retention of the stent on plaque deposited on arterial walls. This may cause the stent to cause some damage to the interior lining of healthy vessels.

Stents can be viewed as scaffoldings, of generally cylindrical symmetry, that function to physically support, and, if desired, expand the wall of the passageway. Typically, a stent consists of two or more struts or wire support members connected together into a lattice-like or open weave frame. Most stents are compressible for insertion through small cavities, and are delivered to the desired implantation site percutaneously via a catheter or

similar transluminal device. Once at the treatment site, the compressed stent is expanded to fit within or expand the lumen of the passageway. Stents are typically either self-expanding or are expanded by inflating a balloon that is positioned inside the compressed stent at the end of the catheter. Intravascular stents are often deployed after coronary angioplasty procedures to reduce complications, such as the collapse of arterial lining, associated with the procedure.

Stents have a lattice-like structure, which leaves spaces defined by the struts that form the stent. Such spaces can allow plaque from the lesion to fall through the stent and enter the blood stream during stent deployment. The spaces can also permit malignant tissue growth through the stent openings into the body passageway and can allow undesired contact between blood flowing through the blood vessel and damaged portions of the vessel. Covered stents, in which a polymeric material surrounds and is attached to the stent, have been proposed to alleviate the problems associated with stent openings.

Diseased vessels are also treated with grafts. Grafts are generally tubular in morphology and are used to replace or create an anatomical passageway to provide a new conduit for fluid, e.g. blood. Grafts are often made from a portion of a vein, but can also be constructed from a synthetic material to form a synthetic graft. Like stents, synthetic grafts can be positioned percutaneously via a catheter, for instance, to be placed at the site of an aneurysm to prevent further dilation and possible rupture of the diseased vessel. In certain instances, the graft material alone does not provide enough structural support for the graft, causing the graft to at least partially collapse and occlude or impede the flow of blood through the

vessel. Grafts may be used with stents. For those cases wherein the graft material is synthetic, the combined structure is sometimes referred to as a synthetic stent-graft. Stents are also placed at the ends of synthetic grafts to help secure the ends of the synthetic graft to vessel walls.

The present invention pertains to a manner of arranging the flexible connectors of a stent to reduce the friction between the stent and the wall of the vessel during delivery.

The present invention also reduces the likelihood of protruding edges that occur when the stent is flexed around a curve which increase to a certain degree the possibility of retention of the stent on plaque deposited on arterial walls.

SUMMARY OF THE INVENTION

The present invention is generally directed to the arrangement of the flexible connectors of a stent. The present invention further discloses that the arrangement of flexible connectors can cause the extremal dimensions of openings in the expanded stent to be reduced.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a layout view of a prior art stent;

Fig. 2 is a layout view of a stent of the present invention;

Fig. 3 is a schematic view of an "N" shaped connection in both the expanded and unexpanded stents; and

Fig. 4 is a schematic view of a "Z" shaped connection of the present invention in both the expanded and unexpanded stents.

DETAILED DESCRIPTION OF THE INVENTION

Briefly, Fig. 1 is a flat layout of a prior art stent, described by Fischell et al in U.S. Patent No. 6,190,403, having a uniform strut width for the circumferential sets of strut members.

Fig. 2. is a flat layout of the stent of the invention, illustrating the radial strut 12 (along the longitudinal axis) and the flexible strut F (along the longitudinal axis). In this embodiment, adjacent rings of radial struts R_1, R_2 comprise periodic structures which are out-of-phase, meaning that peaks P_1 in one ring R_1 face peaks P_2 in the adjacent ring R_2 and that troughs T_1 in one Ring R_1 face troughs T_2 in the adjacent ring R_2. In the depicted embodiment, flexible struts link adjacent peaks P of the periodic structure of radial struts R. (In a different embodiment, flexible struts can link non-adjacent peaks.) In other embodiments of the present invention, adjacent rings of radial struts comprise periodic structures which are in-phase, meaning that peaks in one ring face troughs in the adjacent ring, and flexible struts can link peak to trough or peak to peak.

Fig. 3. is a schematic of a stent with an N-connector in the unexpanded and expanded state.

Fig. 4. is a schematic of a stent with a Z-connector in the unexpanded and expanded state, which shows a smaller circular area as the connector rotates into the cell.

Angioplasty, either coronary or general vascular, has advanced to become the most effective means for revascularization of stenosed vessels. Balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as laser based treatment, or directional or rotational arthrectomy, have proven to be either of limited effectiveness or dependent on balloon angioplasty for completion of the intended procedure. Restenosis following balloon-based angioplasty is the most serious drawback and is especially prevalent in the coronary artery system.

Many regimens have been designed to combat restenosis, with limited success, including laser based treatment and directional or rotational arthrectomy. Intravascular stenting, however, noticeably reduces the restenosis rate following angioplasty procedures. The procedure for intravascular stent placement typically involves pre-dilation of the target vessel using balloon angioplasty, followed by deployment of the stent, and expansion of the stent such that the dilated vessel walls are supported from the inside.

The intravascular stent functions as scaffolding for the lumen of a vessel. The scaffolding of the vessel walls by the stent serve to: (a) prevent elastic recoil of the dilated vessel wall, (b) eliminate residual stenosis of the vessel; a common occurrence in balloon angioplasty procedures, (c) maintain the diameter of the stented vessel segment slightly larger than the

native unobstructed vessel segments proximal and distal the stented segment and (d) as indicated by the latest clinical data, lower the restenosis rate. Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels; treatments may include adjuvant drug therapy (including drug eluting stents) and other methods mentioned previously.

An example of an early conventional stent is the Palmaz-Schatz® stent made by Cordis Corporation and at least partly described in Schatz, U.S. Pat. 5,195,984 (the Schatz Patent). The stent described in the Schatz Patent consists of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connector member.

Some current stent designs such as the CORDIS BX Velocity ® stent, Cordis Corporation, Miami Lakes, FL, have the required flexibility and radial rigidity to provide an excellent clinical result. The present invention may be viewed as a modification over such stents.

Many current tubular stents use a multiplicity of circumferential sets of strut members connected by either straight longitudinal connecting links or undulating longitudinal connecting links. The circumferential sets of strut members are typically formed from a series of diagonal sections connected to curved sections forming a closed-ring, zig-zag structure. This structure opens up as the stent expands to form the element in the stent that provides structural support for the arterial wall. A single strut member can be thought of as a diagonal section connected to a curved section within one of the

circumferential sets of strut members. In current stent designs such as the BX Velocity ® stent, these sets of strut members are formed from a single piece of metal having a uniform wall thickness and generally uniform strut width. Although a stent with uniform width of the strut members will function, if the width is increased to add strength or radiopacity, the sets of strut members will experience increased strain upon expansion.

FIG. 1 shows a flat layout of an embodiment of a prior art stent described by Fischell et al in U.S. Patent No. 6,190,403. The stent 5 of FIG. 1 is shown in its crimped, pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. The stent 5 comprises end sets of strut members 2 located at each end of the stent 5 and three central sets of strut members 6 connected each to the other by sets of longitudinally extending undulating "N" links 4. The end sets of strut members 2 consist of alternating curved sections 7 and diagonal sections 9. The central sets of strut members 6 located longitudinally between the end sets of strut members 2 consist of alternating curved sections 3 and diagonal sections 8.

In the prior art stent 5, the longitudinally diagonal sections 9 of the end sets of strut members 2 are shorter in length than the longitudinally diagonal sections 8 of the central sets of strut members 6. The shorter diagonal sections 9 will reduce the stiff longitudinal length of metal at the ends of the stent 5 to improve deliverability (by reducing "fish-scaling") and will also increase the post-expansion strength of the end sets of strut members 2 as compared with the central sets of strut members 6. In this prior art stent, the width of the curved sections 3 and 7 and the diagonal sections 8 and 9 are all the same. There is no variation in width within any

set of strut members or between the end sets of strut members 2 and the central sets of strut members 6. The stent 5 is a design well suited to stainless steel having a wall thickness of 0.0045" or greater, such as found in the CORDIS BX Velocity® stent.

Figure 3 is a schematic of a stent with a flexible N-connector in both the unexpanded and the expanded state. The longitudinally extending undulating N links define a certain circular area between each pair of N links, shown as a circle "O" and illustrated in the "expanded" state in Figure 2.

Figure 4 is a schematic of a stent with a flexible Z-connector in both the unexpanded and the expanded state. The longitudinally extending undulating Z links define a certain circular area illustrated in the "expanded" state in Figure 3. One can see that there is a smaller circular area as the connector rotates into the cell. A Z link, or something with the symmetry of a "Z", will manifest greater expansion in the circumferential direction than an N-link. This greater extension will lower the distance of closest approach between links about the circumference. The nature of the extension of the Z link, relative to the extension of the N-link, will decrease the distance of closest approach between consecutive Z links along the vertical axis, relative to the distance of closest approach of consecutive N links. The nature of the Z-link, or symmetry related link, relative to the N link, will create a smaller gap between links. The lowered dimension results in enhanced screening or filtering capability.

Thus, an embodiment of the present invention discloses an undulating longitudinal connecting link nominally in the shape of a "Z", as

distinct from the prior art which discloses an undulating longitudinal connecting link in the shape of an "N".

Embodiments of the longitudinal connecting link of the present invention encompass undulating connecting links with the following properties. In a two dimensional representation as in Figure 1, define a Cartesian coordinate system wherein the "x" axis (or horizontal axis) is the longitudinal axis of the figure and the "y" axis (or vertical axis) is the circumferential axis of the figure. An embodiment of the present invention encompasses undulating links wherein each individual link comprises at least two points wherein the tangent is parallel to the y or circumferential axis. In terms analogized to calculus, one would say that each individual link comprises at least two points wherein the first derivative on this graph is infinite.

Embodiments of the longitudinal connecting links comprise an individual undulating link wherein the link has at least two points wherein the tangent is "vertical" and wherein each undulating connecting link posseses a midpoint, such that at the intersection of that midpoint with a circumference of the stent (a vertical line in the two dimensional representation) there is inversion symmetry with respect to that intersection taken as the origin of a Cartesian coordinate system. For each point (x,y) of the undulating connecting member, there is a point (-x, -y).